Remarks

Reconsideration of this Application is respectfully requested.

Upon entry of the foregoing amendment, claims 6-9 and 11-16 are pending in the application, with 6, 9 and 11 being the independent claims. Claims 1-5, 10 and 17-23 are withdrawn from consideration. Claims 6, 7, 9 and 11 are sought to be amended. These changes are believed to introduce no new matter, and their entry is respectfully requested.

Based on the above amendments and the following remarks, Applicants respectfully requests that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

I. Support for Amendments

Support for the amendments to claims 6, 7, 9 and 11 can be found in the specification at, for example, page 5, lines 12-13 and 22-28 and page 8, lines 11-12.

II. Objection of Specification

At page 2 of the Office Action, the Examiner objected the instant specification because the specification did not provide information about the application to which priority was claimed. In response, Applicants have amended the specification to include a specific reference to a prior application from which priority is claimed, in accordance with 37 C.F.R. § 1.78. Accordingly, withdraw of this objection is respectfully requested.

III. Rejections under 35 U.S.C. § 112, first paragraph

At page 3 of the Office Action, the Examiner rejected Claims 11-16 under 35 U.S.C § 112, first paragraph, as failing to provide adequate written description of the invention and failing to provide an enabling disclosure. According to the Examiner:

> The specification does not provide evidence that the claimed biological material is (1) known and readily available to the public; (2) reproducible from the written description, e.g. sequenced; or (3) deposited.

Office Action, paper No. 9, page 3.

Assurance is hereby given that the bacterial strains, L63.148, L64.132, L69.53, L69.74 and L69.100, were deposited under the terms of the Budapest treaty on November 5, 1998. The deposits were made at the United States Department of Agriculture-Agriculture Research Service-National Center for Agriculture Utilization Research (USDA-ARS-NCAUR), 1815 North University Street, Peoria Illinois 61604-3999, and given accession numbers NRRLB-30059, NRRLB-30060, NRRLB-30061, NRRLB-30062 and NRRLB-30063, respectively. Assurance is also hereby given that the deposited bacterial strains are the same as the bacterial strains described in the specification and that the deposited bacterial strains were in the Applicant's possession at the time of filing (see Exhibits 1-5:International Receipt Forms for deposited bacterial strains). Finally, assurance is hereby given that all restrictions on the availability to the public of the deposited bacterial strains will be irrevocably removed upon the granting of a patent, subject to 37 C.F.R. § 1.808(b). Withdraw of this rejection is respectfully requested as the Applicants have provided the necessary assurances required by the Examiner for USDA-ARS-NCAUR Deposit Nos. NRRL B-30059, NRRL B-30060, NRRL B-30061, NRRL B-30062 and NRRL B-30063.

IV. Rejections under 35 U.S.C. § 112, second paragraph

At page 4 of the Office Action, the Examiner rejected Claims 7-9 and 11-16 under 35 U.S.C § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter the Applicants regard as the invention. Although Applicants assert that the claims rejected clearly pointed out the subject matter being claimed, such as "bacterial strain B selected from said mutagenized parental strain," Applicants have amended the claims above, thereby overcoming the rejections. Particular rejections are addressed in more detail below.

Claims 6 and 9 were rejected due to the term "medium." Although Applicants assert that this term is well-known in the art, the language has been amended to clarify that the medium is "bacterial culture medium."

Claim 6 was also rejected due to the language "bacterial strain B selected from said mutagenized parental strain." Applicants assert that this language is clear, especially when read in light of the specification. However, the language has been amended to "a bacterial culture medium containing said mutagenized parental strain."

Claim 11 was rejected for the term "mutant." The language has been amended to clarify that the mutant has "increased amino acid production." This language more clearly provides that the "mutants of (a), (b), (c), (d) or (e)," regardless of the type of mutation, has "an increased production of a desired amino acid," as opposed to mutants, for example, which have either reduced or no production of a desired amino acid.

Claims 8 and 12-16 were rejected for being indefinite because of the indefiniteness of their respective base claims. Claim 6, which Claim 8 indirectly depends from, has been amended to clarify the language "bacterial strain B selected from said

mutagenized parental strain." Similarly, Claim 11, which Claims 12-16 directly depend from, has been amended to particularly and distinctly identify the bacterial strain by its name and to clarify the term "mutants."

For the above-stated reasons, Applicants respectfully request that the rejections be withdrawn.

V. Provisional Double Patenting Rejections

At page 5 of the Office Action, the Examiner rejected Claims 6-8 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 20, 21-26, 29, 30, 49-52, 54, 57 and 58 of the co-pending application, SN 09/962,303 (hereafter "the '303 application"). According to the Examiner:

> Although the conflicting claims are not identical, they are not patentably distinct from each other because of the overlapping scope.

Office Action, paper No. 9, page 5.

Applicants respectfully traverse. Applicants assert that the '303 application does not encompass a raffinate-resistant bacterial strain that produces amino acids and, thus, claims 6-8 are patentably distinct. The '303 application creates threonine producing microorganisms by mutagenesis after inserting a threonine operon, which is operably linked to a non-native promoter. The '303 application also creates threonine producing microorganisms that are threonine raffinate-resistant after inserting a threonine operon, which is operably linked to a non-native promoter. However, the '303 application does not select a raffinate-resistant bacterial strain and produce amino acids after mutagenesis, as the claims of the present invention recite (see Claim 6 (c)). Thus, the claimed

invention is quite distinct from the '303 application. Accordingly, Applicants respectfully request that the rejection be withdrawn.

In addition, at page 5, the Examiner rejected Claims 6-8 under the judicially created doctrine of obviousness-type double patenting over claims 1-12 of the patent, U.S. Patent No. 5,939,307 (hereafter "the '307 patent"). According to the Examiner:

> Although the conflicting claims are not identical, they are not patentably distinct from each other, because strain claimed in the instant claims are encompassed in the scope of the claims in the issued patent.

Office Action, paper No. 9, page 5.

Applicants respectfully traverse. Applicants assert that the '307 patent does not encompass a raffinate-resistant bacterial strain that produces amino acids and, thus, claims 6-8 are patentably distinct. The '307 patent creates amino acid producing microorganisms after inserting a non-native promoter to control the expression of the respective amino acid. The '307 patent also creates amino acid producing microorganisms, as described above, that: (1) contain a feedback-resistant aspartate kinase and/or (2) an antibiotic resistance marker gene (i.e. borrelidin). Although the '307 patent genetically modifies microorganisms to produce amino acids, the '307 patent does not select a raffinate-resistant bacterial strain and produce amino acids after mutagenesis, as the claims of the present invention recite (see Claim 6 (c)). Thus, the claimed invention is quite distinct from the '307 patent. Accordingly, Applicants respectfully request that the rejection be withdrawn.

VI. Rejections under 35 U.S.C. § 102

At page 5 and 6 of the Office Action, the Examiner rejected Claims 6-8 under 35 U.S.C § 102(b) as allegedly being anticipated by Sahm *et al.*, *Construction of L-Lysine-, L-Threonine-, or L-Isoleucine-Overproducing Strains of Corynebacterium glutamicum,* 782 ANN. N.Y. ACAD. SCI. 25 (1996) (hereinafter "Sahm"). According to the Examiner:

> Claims 6-8 are product-by-process claims and are not limited to the manipulations of the recited steps, but only the structure implied by the steps.

Office Action, paper No. 9, page 6.

The Examiner further states:

> Sahm *et al.* taught a mutant *Corynebacterium glutamicum* strain that produced an amino acid, such as, L-Lysine, L-threonine or L-isoleucine. The mutant strain was produced by mutagenesis.

Office Action, paper No. 9, page 6.

Applicants respectfully traverse. Applicants assert that Sahm cannot anticipate the claims of the present invention because it does not create a raffinate-resistant bacterial strain that produces amino acids. Although Sahm creates bacterial strains that overproduce l-Lysine, l-Threonine or l-Isoleucine, via overexpression of genes that are involved in amino acid biosynthesis, Sahm does not produce a raffinate-resistant bacterial strain, as the claims of the present invention recite (see Claim 6 (c)). Thus, Sahm cannot anticipate the present invention because it does not teach or suggest the creation of a microorganism that is raffinate-resistant and produces amino acids. In this regard, the claimed invention is quite distinct from Sahm. Accordingly, Applicants respectfully request that the rejection be withdrawn.

Conclusion

All of the stated grounds of objection and rejection have been properly accommodated or traversed. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

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Version with markings to show changes made

In the Claims:

6. (Once amended) A bacterial strain B that produces an amino acid, wherein said strain was produced by a process [wherein] comprising:

(a) subjecting a parental bacterial strain A [is subjected] to mutagenesis;

(b) culturing the mutagenized parental strain [is contacted] with a bacterial culture medium containing at least about 1% raffinate based on ammonia sulfate content;

(c) selecting a raffinate-resistant bacterial strain B [is selected] from the bacterial culture medium containing said mutagenized parental strain of part b[;and] that has an impaired raffinate resistance when compared to that of strain B

[(d) amino acid production of said bacterial strain B is determined].

7. (Once amended) The bacterial strain of Claim 6, wherein the parental bacterial strain A is selected from the [a] group consisting of the following:

(a) *Corynebacterium sp.*;

(b) *Brevibacterium sp.;*

(c) *Escherichia coli*; and

(d) *Bacillus sp.*

9. (Once amended) A *Corynebacterium* [*sp.*] strain, wherein said strain produces

[producing] at least about 10 g/l L-lysine in 24 hours when grown in a bacterial culture medium containing at least about 1% raffinate.

11. (Once amended) An isolated L-lysine producing *Corynebacterium* [bacterial] strain,wherein said strain is selected from the group consisting of:

(a) NRRL B-30059;

(b) NRRL B-30060;

(c) NRRL B-30061;

(d) NRRL B30062;

(e) NRRL B-30063; and

(f) mutants of (a), (b), (c), (d) or (e), wherein said mutant has an increased amino acid production of a desired amino acid as compared to the production of the same amino acid in the strain before being mutagenized.